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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/663,272	11/25/1996	LEONARD HARRISON	10308	8910

7590

02/24/2003

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GARDEN CITY, NY 11530

EXAMINER
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EWOLDT, GERALD R 36

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

08/663,272

Applicant(s)

Harrison et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 21, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Jan 21, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 39 and 40

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other:

**DETAILED ACTION**

1. Applicant's amendment and response, filed 1/21/03, is acknowledged.
2. Claims 39 and 40 are pending.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 39 and 40 stand rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of using the claimed peptides, for the reasons of record as set forth in Papers No. 28 and 31, mailed 10/25/01 and 7/15/02, respectively.

Applicant's arguments, filed 1/21/03, have been fully considered but they are not persuasive.

First note that Applicant's assertion that "During the course of [the] interview [12/17/02], the Examiner indicated that Applicants should provide some evidence that the peptides of the present invention (the subject of claims 39 and 40) are not only useful as therapeutic agents but also can be considered useful for other purposes," is not entirely accurate. What the Examiner actually indicated was that said evidence might be helpful in demonstrating that the products of the claims are enabled for at least one of their intended uses.

Applicant argues that support for the use of the peptides of the instant claims in diagnostic methods can be found throughout the specification, e.g., pages 2-3, 7, 9, and Examples 4-6. It remains the Examiner's position that said support is insufficient to enable all of the peptides encompassed by the instant claims. Applicant has failed to establish any significant link between the *in vitro* assays of the specification and the diagnosis or treatment of IDDM.

5. Claim 39 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the

inventor(s) had possession of the claimed invention at the time the application was filed Paper No. 31, mailed 7/15/02. This is a new matter rejection.

Applicant's arguments, filed 1/21/03, have been fully considered but they are not persuasive. Applicant argues that SEQ ID NOS: 1 and 2 are each 13 amino acids, thus, supporting the amended claim. It is the Examiner's position that the 2 disclosed species are insufficient written description of the unlimited number of peptides encompassed by X<sub>2</sub> given the recitation of "derived from or contiguous within the amino acids 506-518."

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.



G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
February 23, 2002